

PHARMACY BOARD[657]

Notice of Intended Action

Twenty-five interested persons, a governmental subdivision, an agency or association of 25 or more persons may demand an oral presentation hereon as provided in Iowa Code section 17A.4(1)“b.”

Notice is also given to the public that the Administrative Rules Review Committee may, on its own motion or on written request by any individual or group, review this proposed action under section 17A.8(6) at a regular or special meeting where the public or interested persons may be heard.

Pursuant to the authority of Iowa Code sections 147.76 and 272C.3, the Board of Pharmacy hereby gives Notice of Intended Action to amend Chapter 8, “Universal Practice Standards,” Iowa Administrative Code.

The amendment was approved at the April 29, 2010, regular meeting of the Board of Pharmacy.

The proposed amendment rescinds current rule 657—8.33(147,155A) and proposes adoption of a new rule regarding the administration of immunizations by pharmacists. The proposed rule defines terms used in the rule and establishes training and education requirements to qualify a pharmacist as authorized to administer vaccines pursuant to the rule. The proposed rule establishes the requirements for administration of influenza and pneumococcal vaccines via written protocol and for the administration of other vaccines via patient-specific prescription. Requirements are established for the documentation and recording of vaccine administration, reporting of the administration to the Immunization Registry Information System (IRIS), and reporting of serious complications to the patient’s primary care physician and to the Vaccine Adverse Event Reporting System (VAERS).

Requests for waiver or variance of the discretionary provisions of these rules will be considered pursuant to 657—Chapter 34.

Any interested person may present written comments, data, views, and arguments on the proposed amendment not later than 4:30 p.m. on July 30, 2010. Such written materials may be sent to Terry Witkowski, Executive Officer, Board of Pharmacy, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688; or by E-mail to terry.witkowski@iowa.gov.

This amendment is intended to implement Iowa Code sections 147.76, 155A.3, 155A.4, and 272C.3. The following amendment is proposed.

Rescind rule 657—8.33(147,155A) and adopt the following new rule in lieu thereof:

657—8.33(147,155A) Administration of immunizations by pharmacists. An authorized pharmacist may administer, pursuant to a prescription or medication order issued by the treating physician authorizing immunization for that patient, immunizations included on the ACIP immunization schedules. An authorized pharmacist may administer, via written protocol, seasonal influenza immunizations and pneumococcal vaccines for adults and adolescents ten years of age and older. An authorized pharmacist may administer, via written protocol to treat or prevent an epidemic or pandemic, influenza and pneumococcal vaccines for patients over the age of six months following a determination of need or declaration of an epidemic or pandemic issued by the department of public health, the CDC, or other state or national authority.

8.33(1) Definitions. For purposes of this rule, the following definitions shall apply:

“*Advisory Council on Immunization Practices*” or “*ACIP*” means a professional advisory body of the Centers for Disease Control and Prevention (CDC) that makes recommendations for the routine administration of vaccines to adults and children in the civilian population.

“*Authorized pharmacist*” means an Iowa-licensed pharmacist who has successfully completed an organized course of study in a college or school of pharmacy or an Accreditation Council for Pharmacy Education (ACPE)-approved continuing pharmaceutical education program on vaccine administration that:

1. Requires documentation by the pharmacist of current certification in the American Heart Association or the Red Cross Basic Cardiac Life Support Protocol for health care providers;

2. Is an evidence-based course that includes study material and hands-on training and techniques for administering vaccines, requires testing with a passing score, complies with current Centers for Disease Control and Prevention guidelines, and provides instruction and experiential training in the following content areas:

- Standards for immunization practices;
- Basic immunology and vaccine protection;
- Vaccine-preventable diseases;
- Recommended immunization schedules;
- Vaccine storage and management;
- Informed consent;
- Physiology and techniques for vaccine administration;
- Pre- and post-vaccine assessment and counseling;
- Immunization record management; and
- Management of adverse events, including identification, appropriate response, documentation, and reporting.

“*IRIS*” means the immunization registry information system established within the Iowa department of public health for the secure storage of patient immunization histories.

“*Local provider service area*” means the area including the county in which the provider regularly practices plus the counties contiguous to the county of practice.

“*Serious complication*” means a complication that requires medical or therapeutic intervention to effectively protect the patient from additional risk, morbidity, or mortality.

“*Vaccine*” means a specially prepared antigen which, upon administration to a person, will result in immunity.

“*VAERS*” means the Vaccine Adverse Event Reporting System established by the Centers for Disease Control and Prevention and the Food and Drug Administration to collect and analyze information about adverse events that occur following the administration of vaccines.

8.33(2) Administration of vaccines via written protocol. A written protocol or protocols for pharmacist-administered immunizations shall be established between an Iowa-licensed physician and one or more authorized pharmacists within the physician’s local provider service area with whom the physician has a working relationship. A written protocol shall be updated at least annually and shall include the following:

a. A statement identifying the individual physician who shall be available through direct telecommunication for consultation, assistance, and direction, or who shall provide physician backup to provide these services when the identified physician is not available, and who is authorized to prescribe drugs for immunization administration;

b. A statement identifying the individual authorized pharmacist or pharmacists;

c. A statement that forbids an authorized pharmacist from delegating the administration of adult immunizations to anyone other than another authorized pharmacist, a registered pharmacist-intern under the direct personal supervision of an authorized pharmacist, or a licensed nurse;

d. A statement identifying the vaccines that may be administered by an authorized pharmacist, the dosages, and the route of administration;

e. A statement identifying the activities an authorized pharmacist shall follow in the course of administering adult immunizations, including:

(1) Procedures for determining if a patient is eligible and has no contraindications to receive the vaccine;

(2) Procedures for determining the appropriate scheduling and frequency of drug administration in accordance with applicable guidelines;

(3) Procedures for record keeping and long-term record storage including manufacturer, batch, or identification numbers;

(4) Procedures to follow in case of serious complications or life-threatening reactions; and

(5) Procedures for the pharmacist and patient to follow in case of reactions following administration;

f. A statement describing reporting requirements pursuant to subrule 8.33(3).

8.33(3) *Reporting.* An authorized pharmacist shall be responsible for reporting the administration of immunizations within 30 days to IRIS. An authorized pharmacist may delegate the preparation and submission of IRIS reports to another member of the pharmacy's staff but the authorized pharmacist shall be responsible for ensuring timely and complete reporting. Immunizations administered via protocol as well as immunizations administered pursuant to an individual prescription shall be reported. In case of serious complications, the authorized pharmacist shall notify the patient's primary care physician, when known, within 24 hours and shall submit a VAERS report.

8.33(4) *Records and documentation.* All records regarding pharmacist administration of immunizations via protocol, and documentation evidencing that each authorized pharmacist has completed the education, training, and certification requirements of an authorized pharmacist, shall be maintained in the pharmacy and shall be available for inspection and copying by the board or its representative for at least two years from the date of the record. If an authorized pharmacist identified in the protocol delegates the administration of immunizations pursuant to paragraph 8.33(2) "c," a log shall be maintained identifying all individuals who administered immunizations pursuant to that delegated authority, including the dates and times those individuals administered immunizations and the signature of the delegating pharmacist.

This rule is intended to implement Iowa Code sections 147.76, 155A.3, 155A.4, and 272C.3.